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December 8, 2011

VIA EMAIL

Steven Bradbury
Director, Office of Pesticide Programs
U.S. Environmental Protection Agency.
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dr. Kenneth Portier, Chair
EPA FIFRA Scientific Advisory Panel
c/o Joseph Bailey, Designated Federal Officer
Office of Science Coordination and Policy
(7201M)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: FIFRA Rodenticide Scientific Advisory Panel Meeting

Dear Dr. Bradbury and Dr. Portier:

We represent Reckitt Benckiser LLC ("Reckitt" or "the Company") concerning EPA's draft Notice of Intent to Cancel and Notice of Denial of Registrations for Certain Rodenticide Bait Products ("draft Notice"). We are writing to express our appreciation for the opportunity to provide Reckitt's perspective on EPA's draft Notice to the Scientific Advisory Panel ("SAP" or "Panel") during its meeting November 29 to December 1, 2011. A great deal of information was provided to the SAP over a short period of time, and we were impressed by EPA's professionalism and efficiency in managing the SAP proceedings, especially in light of the complexity of the issues involved.

We also wanted to take this opportunity to clarify a few issues that arose during the SAP deliberations. In light of the quantity of information and the large number of topics that were covered, it is not surprising that there were a few areas where additional clarification may be helpful to the SAP. In order to ensure that this information is timely received by both EPA and the SAP, this letter is addressed to Dr. Bradbury and to Dr. Portier (c/o Joseph Bailey, the SAP Designated Federal Officer -- "DFO"). The list below is not intended to be comprehensive, but it addresses some potentially significant issues -- raised by Reckitt and by EPA -- where we believe that additional information or clarification will be helpful to the SAP.

First, during his remarks to the SAP, Reckitt Benckiser's Senior Vice President, Bill Mordan described the final EPA Risk Mitigation Decision for Ten Rodenticides ("RMD"), issued in June 2008, as having been published without formal public comment. Mr. Mordan was referring to the fact that the final RMD contained policy changes not contained in the draft RMD issued in 2007, and that these changes were not subject to public comment. We recognize that the draft RMD was subject to public comment, and Reckitt provided public comments to EPA on that document. To the extent that any members of the SAP construed Mr. Mordan to be stating that the draft RMD was not subject to public comment, we wanted to take this opportunity to clarify his statement.

Second, on November 30, 2011, Dr. Edward Odenkirchen of EPA stated that the EPA Office of Pesticide Programs Environmental Fate and Effects Division ("EFED") had provided a response to the study by The Cadmus Group Inc. ("Cadmus") entitled "A Probabilistic Assessment of the Risk of Brodifacoum to Non-target Predators and Scavengers," dated September 10, 2004 ("the Cadmus study"), but that EPA received no response to this EFED report from the registrants. Dr. Odenkirchen's statement was inaccurate. Cadmus prepared a response to the EFED analysis, and Syngenta provided this response to EPA in August 2007. Reckitt and Syngenta made this response available to the SAP on December 1, 2011, and we trust EPA will clarify this for the Panelists and for purposes of the final SAP meeting record.

Third, during a break between sessions of the SAP meeting, Dr. William Jacobs of EPA pointed out to Dr. Colin Prescott, an expert retained by Reckitt, that Dr. Prescott may have inadvertently mischaracterized tabulated data in a paper by S. D. Palmateer that was referenced in the paper that Dr. Prescott prepared for the SAP. Dr. Prescott has reviewed the Palmateer paper, and has concluded that Dr. Jacobs is correct. A revised version of Dr. Prescott's paper is enclosed. We would appreciate your passing along to the Panelists the corrected document and placing a copy into the SAP docket.

Fourth, at the SAP sessions November 30 and December 1, Dr. Bradbury provided to EPA an overview of the SAP's role in advising EPA on the draft Notice. While Dr. Bradbury discussed certain provisions of FIFRA generally, as well as his understanding of the role of the SAP, neither he nor anyone else from EPA provided the SAP with the actual relevant provisions of FIFRA. This is significant not only because key nuances may be lost in paraphrasing statutory text, but also because the summary Dr. Bradbury provided left out certain critical elements in these provisions of FIFRA. For example, in discussing the definition of the phrase "unreasonable adverse effects on the environment," Dr. Bradbury did not mention that, in the case of public health pesticides

such as rodenticides, FIFRA requires EPA to "weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide." *See* 7 U.S.C. § 136(bb).

Similarly, Dr. Bradbury also stated that it is the role of the Department of Health and Human Services ("HHS"), and not the SAP, to comment on the potential loss of benefits, such as the impacts on public health and the spread of rodent-borne diseases, that could result from cancellations of consumer use rodenticides discussed in the draft Notice. However, nothing in FIFRA suggests such a distinct bifurcation between the role of the SAP and the role of HHS in advising EPA on draft cancellation notices. Indeed, FIFRA states explicitly that the SAP shall "comment as to the impact on health and the environment of the action proposed" by EPA, *see* 7 U.S.C. § 136w(d), a scope self-evidently broad enough to encompass a discussion of benefits. EPA itself implicitly acknowledged that the SAP may consider the comparative benefits of rodenticide products by including among the charge questions two questions related to comparative efficacy. *See* Charge Questions 10 and 11.

Because EPA's statements on this issue to the SAP may have been confusing, we are attaching to this letter excerpts from the provisions of FIFRA that directly address the role of the SAP in advising EPA on cancellation actions. (We provided these to Mr. Bailey on December 1, 2011, but we are uncertain if they were distributed to the entire Panel. We would appreciate if these excerpts from FIFRA can be distributed to the Panel).

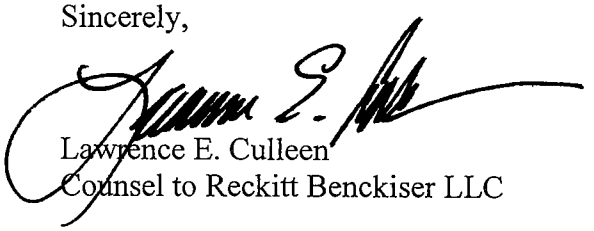
Fifth, we are concerned that the SAP may not have been provided a clear description of the specific uses of Second Generation Anti-Coagulant Rodenticides ("SGARs") that are currently registered, and that will continue to be registered even if EPA's proposed cancellation actions succeed. Dr. Odenkirchen told the panel that no agricultural uses for SGARs are currently registered. While this may be a correct statement as applied to broadcast field uses, it does not address the continued use of SGARs by farmers in and around (within 50 feet of) agricultural buildings that will continue to be permitted by EPA even after the completion of the actions proposed in the draft Notice. Moreover, EPA did not describe the physical form (e.g. both pellets and blocks) of the second generation anticoagulant products that may remain registered for use by the general public in these agricultural applications following the RMD. During the SAP meetings, the Panelists were not specifically advised of these continuing agricultural uses (which require no license for an individual to apply), and the physical forms of the products that may be used for such purposes (such as pellets). Such uses

contrast significantly with the household uses of SGARs, which EPA's draft Notice proposes to cancel.

Sixth, Dr. Odenkirchen was asked to explain the apparent decline in the number of incidents depicted in a bar graph prepared by EPA describing wildlife incidents that were reported in certain years. We understood Dr. Odenkirchen to suggest that the decline in reports which began in approximately 2000 and continues to the present may have been due to the effective date of amendments EPA made to the requirements governing FIFRA § 6(a)(2) reporting. To be clear, the Agency published the amendments to which Dr. Odenkirchen referred in September 1997; EPA issued technical corrections in 1998, which delayed the effective date of the amended requirements until August 1998. Contrary to the impression that might have been given by the Agency's remarks to the Panel, the requirements for reporting incidents involving nontarget organisms were strengthened, not relaxed, at that time such that "any single incident involving humans or nontarget organisms" must be reported if the basic reporting criteria are met. 62 Federal Register 49370, 49382 (September 19, 1997). Prior to that time, reports needed to be filed generally only when multiple incidents involving nontarget organisms had been observed. Thus, while the strengthening of the reporting requirements might reasonably explain the increase in reports in the period immediately following the effective date, it is unlikely to explain the steady decline in such incidents during the course of the past decade.

Once again, thank you for providing us an opportunity to offer comments to the SAP. We appreciate the effort that went into arranging for the Panel and managing the formidable logistics of such an undertaking. In the event you wish to further discuss any of the issues identified in this letter, or any other issues that arose during the SAP meetings, please feel free to call me at 202-942-5574.

Sincerely,



Lawrence E. Culleen
Counsel to Reckitt Benckiser LLC

cc: Richard Keigwin, USEPA/OPP
Robert Perlis, USEPA/OGC

Enclosures

MEETING OF THE FIFRA SCIENTIFIC ADVISORY PANEL
TO CONSIDER AND REVIEW SCIENTIFIC CONCLUSIONS ASSOCIATED WITH
EPA'S DRAFT NOTICE OF INTENT TO CANCEL TWENTY HOMEOWNER RODENTICIDE BAIT PRODUCTS

NOVEMBER 29 THROUGH DECEMBER 1, 2011

DOCKET EPA-HQ-OPP-2011-0718

RECKITT BENCKISER LLC COMMENTS CONCERNING THE DRAFT NOTICE OF INTENT TO CANCEL

VOLUME VII: THE EFFECT OF RODENTICIDE FORMULATION ON EFFICACY: A COMPARISON OF PELLET AND WAX BLOCK FORMULATIONS MANUFACTURED IN THE UNITED STATES, EUROPE, AND ELSEWHERE

Revised December 7, 2011

Paper Prepared for the EPA FIFRA Scientific Advisory Panel

Report

The effect of rodenticide formulation on efficacy: a comparison of pellet and wax block formulations manufactured in the US, Europe and elsewhere

Paper prepared at the request of:

Arnold and Porter LLP
555 Twelfth Street NW
Washington, DC 20004-1206
USA

Paper prepared by:

Dr Colin V Prescott

Director – Vertebrate Pests Unit
University of Reading
School of Biological Sciences
Harborne Building
Whiteknights
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November 14, 2011

Revised December 7, 2011

Contents

Author Résumé

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Ph.D. University of Greenwich
Thesis: Factors responsible for the maintenance of the chalk grassland plagioclimax, on Shorehill Down, Kemsing, Kent (1988).

Member - Society of Biology (C.Biol., M.I.Biol.)	September 1985
Member of the British Ecological Society	September 1981
Member of the Association for the Study of Animal Behaviour	
Member of the Mammal Society	
Fellow of the British Trust for Ornithology	
Member of the Royal Society for the Protection of Birds	

Relevant Experience

Main area of research – the anticoagulant rodenticides, their mode of action, their biphasic elimination, their impact on primary and secondary non-target species, and the development of physiological resistance.

I have been investigating the development of physiological resistance in Norway rats and House mice, and have developed a standardised methodology for a wide range of anticoagulant active ingredients, that is based on blood clotting activity. The methodology can both identifying the resistance and then quantify the likely effect on field efficacy, by providing an estimate of the resistance factor. In addition, there is a new molecular methodology that we now use routinely, that can identify a number of mutations of the target enzyme (the vitamin K epoxide reductase). We are now involved in a number of projects that are mapping the distribution of the different types of physiological resistance across the UK, and elsewhere.

I have been working on the impact and control of rodents in Pakistan, in Malaysia, in Mexico, in Chile and in the Philippines. I am particularly interested in the non-target impact of anticoagulants on birds, and am supervising a BBSRC CASE studentship in this area. I have been the University supervisor of a number of MSc students working on mammals and birds: on the impact and eradication of alien species on Lambay Island near Dublin (3 students); on the impact and eradication of alien species on Great Salvage Island (1 student); on the habitat use and feeding ecology of native rodents in the Ifugao rice terraces in the Philippines (1 student); and on the use of social attraction techniques in an attempt to establish a Sooty Tern colony on Dennis Island in the Seychelles (4 students); plus others.

- Associate Editor of the Journal 'Pest Management Science'
- BTO 'A' ringer with training endorsement, plus endorsements to ring pulli, and to use mist nets and woosh nets.
- Natural England Licence Holder – Dormouse – to check nest boxes, for handling and fur-clipping.
- Natural England Licence Holder - Educational licence to authorise student handing of pulli Blue tit and Great tit.
- Natural England Licence Holder – Bat species – to extract from mist nets, and to photograph and identify prior to release.
- Over the past 22 years I have managed numerous Industrial R & D Contracts.

This paper was prepared for the EPA FIFRA Scientific Advisory panel meeting November 29 to December 2, 2011, to review EPA's draft Notice of Intent to cancel certain rodenticide products. This paper reviews data and studies comparing the efficacy of rodenticide bait in block and pellet form. Its principal finding is that bait in pellet form is significantly more effective in rodent control than bait in block form, and that the U.S. E.P.A. appears to have substantially understated the loss of efficacy due to requiring all rodenticide bait to be in block form as part of its 2008 Risk Mitigation Decision for Ten Rodenticides ("RMD") and its 2011 draft Notice of Intent to Cancel and Deny Registrations.

Introduction

Typically, rodenticides are palatable formulations that contain specific chemical active ingredients that are known to be toxic once ingested by the rodent pest species. The most important features of a rodenticide are its toxicity and its palatability, both of which are largely assessed in the laboratory. Much of the considerable effort involved in the laboratory evaluation of rodenticides is aimed at meeting the increasing demands of the regulatory bodies, with the basic data requirement for registration (i.e. specifications, efficacy and toxicity) being largely standardized (Johnson and Prescott, 1994). In the United States, rodenticides are evaluated using the Environmental Protection Agency Guidelines (EPA, 1982), while in Europe, test methods are based on the BPD (2009).

The RMD, published by the Environmental Protection Agency in May 2008, has proposed fundamental changes to the methods of rodent control available to residential consumers in the United States for the control of commensal rodents in and around buildings. One important change is the removal of all particulate baits and the requirement for all bait placements to be in block or paste form than can be securely held in bait stations. The purpose of this document is to present an analysis of efficacy data generated at the University of Reading that compares a range of pellet and wax block formulations, to provide insight into the potential effects of removing particulate rodenticide formulations from the residential consumer market.

Laboratory Feeding Tests in the UK

When conducting laboratory feeding tests, it is important to standardize as much as possible for the test animals that are used, and for the cage environment in which the tests are conducted. Logistically, laboratory strains of Norway rat and house mice are preferred for studies on caged rodents, because they are readily available, and are easy to handle in a laboratory environment. Although tests on wild derived strains will provide results that can be considered more closely associated with field control, and in some countries is the only option available, data generated will have greater variance, because of the behaviour of the animals in the alien environment of a laboratory, thus making it more difficult to demonstrate statistically significant differences between formulations.

Stringent control of environmental conditions and proper animal care techniques are also extremely important for the generation of meaningful results, because of their potential effect on animal behaviour. In the UK, this is regulated by the UK Government Home Office, under the regulation of the Animals (Scientific Procedures) Act (1986). All personnel conducting animal tests are required to have a Home Office Personal License, which specifies the techniques and procedures that person is competent to carry out. In addition the Principal Investigator must possess a Home Office Project License that details the protocols for all studies that have a potential adverse effect on the animal.

Unannounced visits by Home Office Inspectors ensure compliance with Home Office requirements for environmental conditions and animal care and welfare. A Home Office and University requirement is for all study protocols to have been previously considered by independent Ethical Review.

Efficacy Assessment at the University of Reading

Laboratory cage tests are designed to evaluate the toxicity and acceptability of rodenticide active ingredients (typically through oral gavage) and of rodenticide formulations (through 'choice' and 'no-choice' feeding tests). This paper specifically reviews 'choice' feeding tests that have been conducted at the University of Reading in order to assess the formulation efficacy of baits in pellet form compared to baits in block form.

The acceptance of anticoagulant rodenticide formulations are routinely tested using groups of animals (usually consisting of five males and five females, individually caged). The animals are conditioned in the test cage for a minimum of four days, so that they become familiar with the test environment and have overcome any neophobia. They are then given the free-feeding choice of the rodenticide formulation and a non-toxic challenge diet over a three or four-day test period, and food consumption is recorded on a daily basis. To this end, the food bowls are removed, weighed, replenished, re-weighed, and returned to the test cage, with the position of the food bowls alternated on a daily basis, in order to overcome the possibility of test animals having a preference for feeding on one side of the cage (exhibiting a side preference), and thus feeding exclusively from one food bowl. In some instances, the "test period" is followed by an "observation period" of up to twenty-one days in order to measure mortality.

In this investigation, the acceptance data was generated against second generation anticoagulant rodenticides using either the CD albino Norway rat or the CD-1 albino house mouse (both obtained from Charles River UK Ltd.), and using a challenge diet of Standard EPA Meal.

Formulation acceptance provides a useful indication of the palatability of a rodenticide formulation. It is determined from consumption data when individually caged test animals are given the free feeding choice of the rodenticide formulation and the challenge diet; and is a measure of rodenticide consumption as a percentage of total food consumption over the test period. For individual animals, formulation acceptance varies considerably, and for meaningful comparisons between formulations, mean acceptance values are calculated for the test group over the three or four day test period. The acceptance data presented in this Report are mean acceptance values obtained from test groups rather than values obtained from individual animals.

The test period is either of three or four days duration, which reflects the American and European guidelines respectively. A three day test period was originally adopted for humaneness reasons in tests where animals are terminated at the end of the test period, to avoid animals experiencing the toxic effects of the anticoagulant. Approximately 10% of test animals die as a result of the anticoagulant on the fourth day of test. A significant reduction in food consumption from test day 3 to test day 4 has been reported, which is believed to result from the animals suffering toxicosis (Johnson and Prescott, 1994). Such animals are unlikely to be so discerning in their appraisal of rodenticide palatability.

Results

The Vertebrate Pests Unit (VPU) of the University of Reading routinely conducts efficacy feeding tests using rodenticide products obtained from commercial manufacturers and suppliers. A database is maintained of all rodenticide efficacy data that has been generated since 1989, and the data presented below has been obtained by analysis of that database.

Data available is primarily for six formulations; a US wax block and pellet formulation containing the active ingredient brodifacoum and marketed under the same trade name (pellet formulation #1 and wax block formulation #1); a UK wax block and pellet formulation containing the active ingredient brodifacoum and marketed under the same trade name (pellet formulation #2 and wax block formulation #2); and a UK wax block and pellet formulation containing the active ingredient difenacoum and marketed under the same trade name (pellet formulation #3 and wax block formulation #3). In the first instance, analysis of each of these three formulations was conducted to compare the acceptance of wax block and pellet formulations that had been manufactured by the same company and contained the same active ingredient.

Acceptance of pellet formulation #1 and wax block formulation #1

The data presented in Table 1 was produced using pellet formulation #1 and wax block formulation #1 (manufactured in the US).

Table 1. The mean percentage acceptance of available data for pellet formulation #1 and wax block formulation #1 (containing 50ppm brodifacoum), generated against albino (CD-1 Swiss) House mice and albino (CD) Norway rats, and using Standard EPA Meal as the challenge diet.

Animal Species	Strain	Formulation (US)	Number of 10 animal tests	Mean % Acceptance
House mouse	CD-1 (albino Swiss)	Pellet	42	48.99
Norway rat	CD (albino)	Pellet	46	31.21
House mouse	CD-1 (albino Swiss)	Wax Block	84	16.88
Norway rat	CD (albino)	Wax Block	85	15.10

The combined data for each species and formulation was subjected to the non-parametric Mann-Whitney test. The Acceptance of the Norway rat pellet data was significantly greater than that of the Norway rat wax block data (Mann-Whitney test; $z = 6.946$; $p < 0.001$); and the Acceptance of the house mouse pellet data was significantly greater than that of the house mouse wax block data (Mann-Whitney test; $z = 8.223$; $p < 0.001$).

Acceptance of pellet formulation #2 and wax block formulation #2

The data presented in Table 2 was produced using pellet formulation #2 and wax block formulation #2 (manufactured in the UK).

Table 2. The mean percentage acceptance of available data for pellet formulation #2 and wax block formulation #2 (containing 50ppm brodifacoum), generated against albino (CD-1 Swiss) House mice and albino (CD) Norway rats, and using Standard EPA Meal as the challenge diet.

Animal Species	Strain	Formulation (US)	Number of 10 animal tests	Mean % Acceptance
House mouse	CD-1 (albino Swiss)	Pellet	85	46.12
Norway rat	CD (albino)	Pellet	90	33.26
House mouse	CD-1 (albino Swiss)	Wax Block	54	10.86
Norway rat	CD (albino)	Wax Block	76	14.40

The combined data for each species and formulation was subjected to the non-parametric Mann-Whitney test. The Acceptance of the Norway rat pellet data was significantly greater than that of the Norway rat wax block data (Mann-Whitney test; $z = 10.010$; $p < 0.001$); and the Acceptance of the house mouse pellet data was significantly greater than that of the house mouse wax block data (Mann-Whitney test; $z = 9.321$; $p < 0.001$).

Acceptance of pellet formulation #3 and wax block formulation #3

The data presented in Table 3 was produced using pellet formulation #3 and wax block formulation #3 (manufactured in the UK).

Table 3. The mean percentage acceptance of available data for pellet formulation #3 and wax block formulation #3 (containing 50ppm difenacoum), generated against albino (CD-1 Swiss) House mice and albino (CD) Norway rats, and using Standard EPA Meal as the challenge diet.

Animal Species	Strain	Formulation (US)	Number of 10 animal tests	Mean % Acceptance
House mouse	CD-1 (albino Swiss)	Pellet	36	40.31
Norway rat	CD (albino)	Pellet	39	23.78
House mouse	CD-1 (albino Swiss)	Wax Block	29	17.72
Norway rat	CD (albino)	Wax Block	29	10.27

The combined data for each species and formulation was subjected to the non-parametric Mann-Whitney test. The Acceptance of the Norway rat pellet data was significantly greater than that of the Norway rat wax block data (Mann-Whitney test; $z = 5.407$; $p < 0.001$); and the Acceptance of the house mouse pellet data was significantly greater than that of the house mouse wax block data (Mann-Whitney test; $z = 6.163$; $p < 0.001$).

Acceptance of other pellet and wax block formulations

In addition to the test detailed above on three pellet and three wax block formulations, samples of a total of forty-seven pellet formulations and sixty wax block formulations that were manufactured in the US, the UK and elsewhere, have been received at the University, and subjected to choice tests against either albino (CD-1 Swiss) House mice, albino (CD) Norway rats, or both species, using Standard EPA Meal as the challenge diet.

The acceptance data presented in Table 4 are for the forty-seven pellet formulations, plus the mean acceptance values for pellet formulations #1, #2 and #3 as presented in Table 1, Table 2 and Table 3.

The acceptance data presented in Table 5 are for the sixty wax block formulations plus the mean acceptance values for wax block formulations #1, #2 and #3 as presented in Table 1, Table 2 and Table 3.

The combined acceptance data for each species and formulation was subjected to a Shapiro-Wilk Normality test, and was found not to deviate significantly from Normality.

The mean acceptance of the House mouse pellet data and the House mouse wax block data, and the mean acceptance of the Norway rat pellet data and the Norway rat wax block data were compared using the T test; and the mean acceptance of the pellet data was found to be significantly greater than the mean acceptance of the wax block data, both for House mice ($t = 2.518$; $df = 91$; $p = 0.014$), and for Norway rats ($t = 3.368$; $df = 110$; $p = 0.001$).

Table 4. Choice test data for all pellet formulations tested at the Vertebrate Pests Unit against albino (CD-1 Swiss) House mice and albino (CD) Norway rats using Standard EPA Meal as the challenge diet. Formulations were manufactured in the US, the UK and elsewhere.

		Active	Norway rat	House mouse
Formulation I.D.	**Country**	**Ingredient**	**(%)**	**(%)**
pellet formulation #1	US	brodifacoum	31.21	48.99
pellet formulation #2	UK	brodifacoum	33.26	46.12
pellet formulation #3	UK	difenacoum	23.78	40.31
pellet formulation #4	US	bromadiolone	21.86	22.48
pellet formulation #5	US	bromadiolone	49.84	11.06
pellet formulation #5	US	bromadiolone	35.67	28.94
pellet formulation #5	US	bromadiolone	38.62	25.63
pellet formulation #5	US	bromadiolone	63.18	19.5
pellet formulation #5	US	bromadiolone		36.41
pellet formulation #5	US	bromadiolone	41.86	28.63
pellet formulation #5	US	bromadiolone	52.32	38.59
pellet formulation #6	US	brodifacoum	11.72	15.38
pellet formulation #7	US	difethialone	13.36	18.67
pellet formulation #8	US	bromadiolone	32.77	37.61
pellet formulation #8	US	bromadiolone	19.99	27.54
pellet formulation #9	US	brodifacoum	30.9	44.62
pellet formulation #10	US	diphacinone	9.20	30.49
pellet formulation #11	Brazil	brodifacoum	29.18	
pellet formulation #11	Brazil	brodifacoum	35.84	
pellet formulation #11	Brazil	brodifacoum	25.14	
pellet formulation #11	Brazil	brodifacoum	17.43	12.09
pellet formulation #11	Brazil	brodifacoum	33.47	34.12
pellet formulation #11	Brazil	difenacoum	10.1	16.23
pellet formulation #12	UK	Brodifacoum	22.82	36.77
pellet formulation #12	UK	brodifacoum	17.04	74.59
pellet formulation #13	UK	bromadiolone	12.34	6.28
pellet formulation #14	UK	difenacoum	29.59	51.67
pellet formulation #15	UK	brodifacoum	22.27	39.56
pellet formulation #16	Chile	difenacoum	9.93	44.31
pellet formulation #17	China	brodifacoum	4.51	7.15
pellet formulation #18	Italy	difenacoum	4.5	5.48
pellet formulation #19	Chile	bromadiolone	4.98	12.82
pellet formulation #20	Columbia	brodifacoum	32.93	28.27
pellet formulation #20	Columbia	brodifacoum	23.53	28.81
pellet formulation #21	Peru	brodifacoum	12.21	29.49
pellet formulation #22	Peru	brodifacoum	6.92	10.28
pellet formulation #23	Chile	brodifacoum	27.32	
pellet formulation #23	Chile	brodifacoum	10.48	47.86
pellet formulation #24	Germany	difethialone	20.47	17.65
pellet formulation #25	N-Zealand	brodifacoum	10.65	4.36
pellet formulation #26	Czech.	brodifacoum	35.81	55.94
pellet formulation #27	UK	brodifacoum	38.13	35.64
pellet formulation #28	Peru	brodifacoum	38.14	36.72
pellet formulation #29	UK	Brodifacoum	32.19	29.51
pellet formulation #29	UK	Brodifacoum	39.53	33.99
pellet formulation #29	UK	Brodifacoum	39.07	30.32
pellet formulation #29	UK	brodifacoum	34.97	22.98
pellet formulation #30	China	brodifacoum	10.07	14.4
pellet formulation #31	UK	brodifacoum	24.23	
pellet formulation #32	Czech.	brodifacoum	10.34	31.54

Table 5. Choice test data for all wax block formulations tested at the Vertebrate Pests Unit against albino (CD-1 Swiss) House mice and albino (CD) Norway rats using Standard EPA Meal as the challenge diet. Formulations were manufactured in the US, the UK and elsewhere.

		Active	Norway rat	House mouse
Formulation I.D.	**Country**	**Ingredient**	**(% Acc)**	**(% Acc)**
wax block formulation #1	US	brodifacoum	15.10	16.88
wax block formulation #2	UK	brodifacoum	14.10	10.86
wax block formulation #3	UK	difenacoum	10.27	17.72
wax block formulation #4	US	bromadiolone	3.57	11.80
wax block formulation #4	US	bromadiolone	27.13	8.96
wax block formulation #5	US	bromadiolone	39.05	31.42
wax block formulation #5	US	bromadiolone	30.02	27.17
wax block formulation #5	US	bromadiolone	38.52	
wax block formulation #5	US	bromadiolone	50.74	41.62
wax block formulation #5	US	bromadiolone	25.38	39.33
wax block formulation #6	US	diphacinone	28.20	
wax block formulation #7	US	chlorophacinone	2.53	17.82
wax block formulation #8	US	brodifacoum	17.26	29.57
wax block formulation #8	US	brodifacoum	29.62	38.90
wax block formulation #9	US	diphacinone	24.63	32.85
wax block formulation #10	US	brodifacoum	29.68	
wax block formulation #10	US	brodifacoum	18.70	23.92
wax block formulation #10	US	brodifacoum	40.21	39.98
wax block formulation #11	US	difethialone	28.90	
wax block formulation #11	US	difethialone	28.67	25.74
wax block formulation #11	US	difethialone	19.60	24.89
wax block formulation #12	US	brodifacoum	15.83	1.71
wax block formulation #13	US	bromadiolone	12.41	24.88
wax block formulation #13	US	bromadiolone	15.51	18.50
wax block formulation #14	Australia	coumatetralyl	11.44	14.95
wax block formulation #15	US	diphacinone	18.81	44.76
wax block formulation #16	Australia	brodifacoum	5.65	5.07
wax block formulation #17	Australia	flocoumafen	6.36	26.03
wax block formulation #18	US	diphacinone	34.79	50.25
wax block formulation #18	US	diphacinone	28.24	23.38
wax block formulation #19	France	brodifacoum	6.54	11.80
wax block formulation #20	Greece	brodifacoum	7.10	
wax block formulation #21	Korea	brodifacoum	6.68	20.65
wax block formulation #22	Mexico	warfarin	8.99	14.30
wax block formulation #23	Mexico	bromadiolone		9.99
wax block formulation #23	Mexico	bromadiolone	15.50	19.16
wax block formulation #24	Chile	bromadiolone	10.25	6.90
wax block formulation #25	Malaysia	bromadiolone	9.70	31.78
wax block formulation #26	Germany		7.40	
wax block formulation #27	China	brodifacoum	1.12	1.65
wax block formulation #28	UK		9.15	
wax block formulation #29	UK		4.86	
wax block formulation #30	Spain		11.41	
wax block formulation #31	Brazil	bromadiolone	20.61	10.7
wax block formulation #32	UK		23.81	
wax block formulation #32	UK		14.15	
wax block formulation #33	UK		14.25	
wax block formulation #33	UK	difenacoum	1.74	24.76
wax block formulation #34	Chile		9.27	
wax block formulation #35	New Zealand	brodifacoum	17.16	55.26

Table 5. (continued)

Formulation I.D.	Country	Active Ingredient	Norway rat (% Acc)	House mouse (% Acc)
wax block formulation #36	Portugal		5.13	
wax block formulation #37	Chile	bromadiolone	5.08	0.54
wax block formulation #38	Chile	brodifacoum	3.18	
wax block formulation #39	UK	brodifacoum	20.27	18.57
wax block formulation #40	UK	flocoumafen	11.33	17.72
wax block formulation #40	UK	flocoumafen	18.68	23.67
wax block formulation #40	UK	flocoumafen	17.30	28.74
wax block formulation #41	UK	brodifacoum		22.81
wax block formulation #41	UK	brodifacoum	14.51	10.05
wax block formulation #42	New Zealand	brodifacoum	37.58	13.26
wax block formulation #43	Greece	brodifacoum	12.10	
wax block formulation #44	China	brodifacoum	2.13	2.56

The relationship between acceptance and mortality

For a rodenticide formulation to be effective, it must be both palatable and toxic to the target species. In the laboratory, formulation palatability and toxicity can both be assessed by means of the choice feeding test, where the test period is followed by an observation period of up to 21 days. For any active ingredient, there will be a direct relationship between bait consumption and mortality, and in the choice test, there will be a similar direct relationship between acceptance and bait consumption, but with much greater variability between individual animals of the test group.

Following an analysis of all data generated at the University of Reading, the relationship between acceptance and mortality is presented for 131 choice tests against albino (CD) Norway rats and for 110 choice tests against albino (CD-1) house mice, in Table 6 and Table 7 respectively.

Table 6. The association between percentage acceptance and mean percentage mortality, achieved in three or four day choice tests with 50ppm brodifacoum formulations, against the albino (CD) Norway rat.

Percentage Acceptance Range	**Mean Percentage Mortality**	**Number of Tests**
0-10	42.1	19
10-15	52.5	24
15-20	79.2	12
20-25	85.2	27
25-30	90.0	11
30-40	96.7	30
40-60	100.0	8

Table 7. The association between percentage acceptance and mean percentage mortality, achieved in three or four day choice tests with 50ppm brodifacoum formulations, against the albino (CD-1) House mouse.

Percentage Acceptance Range	**Mean Percentage Mortality**	**Number of Tests**
0-10	37.3	22
10-15	68.0	15
15-20	68.6	7
20-25	93.3	6
25-30	92.5	8
30-40	91.1	24
40-60	98.9	28

Table 8. Summary of the mean percentage acceptance data (with standard deviations) generated in three or four day choice feeding tests, against albino (CD-1) House mice and albino (CD) Norway rat, for the pellet and wax block formulations considered in Tables 1-5 above.

Animal Species	Strain	Formulation	Mean % Acceptance	Standard Deviation
House mouse	CD-1	Pellet formulation #1	48.99	16.44
		Pellet formulation #2	46.12	15.91
		Pellet formulation #3	40.31	10.26
		Pellet formulation #4 - #32	27.83	14.82
Norway rat	CD	Pellet formulation #1	31.21	8.64
		Pellet formulation #2	33.26	8.86
		Pellet formulation #3	23.78	10.11
		Pellet formulation #4 - #32	25.05	14.16
House mouse	CD-1	Block formulation #1	16.88	9.95
		Block formulation #2	10.86	8.49
		Block formulation #3	17.72	6.56
		Block formulation #4 - #32	22.06	13.31
Norway rat	CD	Block formulation #1	15.10	9.62
		Block formulation #2	14.40	7.43
		Block formulation #3	10.27	5.53
		Block formulation #4 - #32	17.56	11.64

Discussion

Analysis of the Norway rat and house mouse acceptance data generated against a challenge diet of Standard EPA Meal clearly demonstrates that pellet formulations achieve a higher acceptance value than wax block formulations. Data generated against three pellet and wax block formulations, each marketed under the same trade name, demonstrated a significantly higher acceptance of the pellet formulation, with p values less than 0.001 in each case.

When the analysis was extended to include other pellet and wax block formulations that had been received and tested at the University of Reading, there was again a significantly higher acceptance of the pellet formulation than the wax block formulation, with a high level of significance with Norway rats ($p = 0.001$) and a slightly lower level of significance with house mice ($P < 0.014$).

Cereal grains, either whole, broken, rolled or ground, are known to produce satisfactory rodenticide baits, and are a principal component of most commercially available rodenticides. With whole grain rodenticides, there is the problem of high concentrations of the active ingredient on the surface of the grain, which can lead to palatability problems if the active ingredient is intrinsically unpalatable (Buckle et al., 1994). Rodenticide pellets overcome this problem to a large extent because the active ingredient is dispersed throughout the matrix of the pellet. However, the main disadvantage of the pellet is their poor weatherability, as they tend to disintegrate if exposed to moisture.

The wax block formulations were developed primarily to overcome the weatherability problems with cereal baits. The blocks are also composed of cereals, to which paraffin wax has been added, usually at a rate of between 15% and 40% by weight (Buckle, 1994). Some are manufactured using melt and cast technology, other are made by a briquetting process, while others are produced by extrusion under pressure. The incorporation of wax enables the formulation to withstand moisture (to varying degrees), but it is generally accepted that they are less palatable to the rodents than formulations based entirely on cereals (Whisson, 1996; O'Connor and Eason, 2000; Quy et al., 2003).

It is therefore within expectation that the above analysis found pellet formulations to be significantly more palatable than wax block formulations. In laboratory choice feeding tests conducted at the University of Reading, individual albino house mice often do not perceive the wax block formulation as a food source, and feed exclusively on the challenge diet, totally ignoring the block formulation over the three or four day test feeding period. In the field, during the course of a treatment, it is not uncommon to pick up wax blocks that have been deposited on open ground. My assumption was that these blocks had originally been placed in burrows, in compliance with the product label, and had then been removed by the rodent. Although there have been few published studies addressing this issue, Quy et al. (2003) recognize the problem of bait transfer and abandonment from burrows by Norway rats, and a DEFRA Project Report (PV1016) entitled "Development of guidelines on best practice for rodenticide use" gives more detailed consideration to the problem (DEFRA, 2002).

There is very little published data comparing the acceptance of pellet and wax block formulations. An online Report from Lincoln University in Christchurch, New Zealand (Ross et al., 2000) presents acceptance data (generated using groups of ten male and ten female Norway rats, and a challenge diet of Standard EPA Meal) for two cereal-based pellet formulations (containing 20ppm brodifacoum) and three cereal-based wax block formulations (one containing 50ppm diphacinone and two containing 20ppm brodifacoum). The three wax block formulations had acceptance values of between 10% and 12%, and the two pellet formulations 28%, which is similar to the data presented in this report.

The EPA would appear to have acknowledged that wax block formulations have a lower palatability, as the US efficacy criteria was set at 80% mortality and 25% acceptance (against standard EPA Meal) for wax block, compared with 90% mortality and 33% acceptance for other dry anticoagulant baits.

Analysis has also been conducted to investigate the effect of acceptance on mortality in the efficacy choice feeding test. The analysis was restricted to all formulations containing 50ppm brodifacoum that were tested against any challenge diet, using the albino (CD) Norway rat and albino (CD-1) house mouse. The analysis revealed that an acceptance of 25-30% and 20-25% (over the 3 or 4 day test period) was required to achieve a mortality of 90% in Norway rats and House mice respectively.

From the mean percentage acceptance data for the pellet and wax block formulations presented in the efficacy tests above, all pellet formulations would be expected to achieve high mortality, but the majority of wax block formulations would not. This analysis, which considers the link between formulation acceptance and mean percentage mortality, is specifically for the active ingredient brodifacoum, one of the more efficacious second generation anticoagulants. For less efficacious second generation anticoagulants, the expectation would be that a higher formulation acceptance

would be required to achieve acceptable mortality in the Choice test; and for the first generation anticoagulants, the effect would pose even more of a problem, particularly for the wax block formulations.

Jacobs (2011) summarised Norway rat laboratory efficacy data for first generation anticoagulants (originally presented by Palmateer, 1974), where 'whole grain', 'meal', 'pellet' and 'wax block' formulations have mean acceptance values of between 20% and 25.1%. Palmateer (1974) does not provide "acceptance data", in the same way as presented by Jacobs (2011). Instead, he presents "bait refusal" data, which is the percentage of total food intake over the test period that is un-poisoned bait (i.e. the challenge diet). For whole grain, meal, pellet and wax block formulations, the bait refusal data presented was 74.9%, 80.0%, 76.8% and 78.3%, which agrees with the acceptance values presented by Jacobs (2011). Thus, only the whole grain formulation meet the US efficacy criteria requirement for wax blocks, and none of the four formulations meet the US efficacy criteria for other dry anticoagulant baits.

I am surprised at the data of Palmateer (1974); in particular that the wax block bait has a higher acceptance than the meal bait. I am also surprised with the low acceptance values for the pellet bait (of 23.2%). Against Norway rats, pellet acceptance data generated at the University of Reading using a similar challenge diet ranged between 23.8% and 33.3%. Similar data was presented by Ross et al., (2000) from work conducted at Lincoln University, where similar pellet efficacy studies achieved an acceptance of around 28%. I would have expected the acceptance data for whole grain, meal and pellet formulations to have been much higher than that reported by Palmateer (1974).

With a database spanning twenty-two years of applied research, all qualifying data has been used, and there has been no attempt to present one or more of the formulations in a good light. A major advantage of the above analysis is that all data has been generated in the same facility using the same strains of test animals (obtained from a reliable source), using the same protocols and study plans, and using the same challenge diet. Variability in any of these parameters could influence the data generated.

For example, the challenge diet should have a consistent and stable palatability, but this can be difficult to achieve, despite rigorous adherence to the EPA Guidelines, primarily because of an initial enhancement of palatability following the grinding of cereals to the required particle size. The University has received samples of "Standard EPA Meal" from laboratories in the US and elsewhere, that clearly do not comply with the EPA Guidelines.

So it would not be surprising if there was a high degree of variability in data generated when formulations are tested at different laboratories. There might also be an expectation of selected data being submitted to regulatory authorities, particularly for wax block formulations (for example, see Peacock and Palmateer, 1979).

Response to Jacobs (2011) IV Effects of Bait Form on the Effectiveness of Commensal Rodenticides

It would be very difficult to develop a viable protocol to investigate the effectiveness of different bait formulations in field situations, because there are so many variables that are impossible to control for. However, in the laboratory environment standardization allows meaningful assessment of formulation acceptance, which can be a useful indication of the palatability of a rodenticide

formulation. The presence of a rodent infestation indicates that the animals have access to an alternative food source, and intuitively, control will be more effective with high formulation palatability, because the rodents will be more likely to feed on the more palatable bait. The laboratory assessment of acceptance is an effective way of assessing the palatability of rodenticide formulations, and from extensive studies conducted at the University of Reading and elsewhere, pellet formulations are intrinsically more palatable than wax block formulations.

In tests reported by Palmateer (1974), overall mortality was 77.4% and not 92%, as reported by Jacobs (2011). I am surprised at the low palatability of the whole grain, meal and pellet formulations; with only the whole grain formulation meeting the US efficacy criteria requirement for wax blocks; and none of the four formulations meeting the US efficacy criteria for other dry anticoagulant baits.

I would expect there to be a high degree of variability in acceptance data generated at different laboratories, but in my experience, pellet and whole grain formulations will generate greater acceptance values than wax block formulations. Peacock and Palmateer (1979) compared efficacy data generated by the US EPA Animal Biology Laboratory with that generated at company laboratories. They found that products always did better in company tests than in EPA tests and proposed a number of reasons to account for this. There is therefore every possibility that data submitted to the EPA for regulatory purposes does not provide a fair efficacy comparison for pellet and wax block formulations.

For rodent control in any section of the market, if available formulations were restricted to wax block formulations I would expect treatment efficacy to be adversely affected. If there were further restrictions on the more effective anticoagulant active ingredients, I would expect this to compound the above adverse effects, and possibly to reduce efficacy below U.S. EPA efficacy criteria.

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Author Curriculum Vitae

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2. University Education

a). BSc. (Hons.) University of Greenwich
Wellington St., London SE18 6PF. 1974 - 1978

b). Ph.D. University of Greenwich
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Thesis: Factors responsible for the maintenance of the chalk grassland plagioclimax, on Shorehill Down, Kemsing, Kent.

3. Professional Institutions.

Member - Institute of Biology (C.Biol., M.I.Biol.)	September 1985
Member of the British Ecological Society	September 1981
Member of the Association for the Study of Animal Behaviour	
Member of the Mammal Society	
Fellow of the British Trust for Ornithology	
Member of the Royal Society for the Protection of Birds	

4. Present Position

Director of the Vertebrate Pests Unit
Principal Research Fellow

Name and Address of Employer:
Section of Environmental Biology
School of Biological Sciences,
The University of Reading,
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5. Relevant Experience

Main area of research – the anticoagulant rodenticides, their mode of action, their biphasic elimination, their impact on primary and secondary non-target species, and the development of physiological resistance.

I have been investigating the development of physiological resistance in Norway rats and House mice, and have developed a standardised methodology for a wide range of anticoagulant active ingredients, that is based on blood clotting activity. The methodology can both identifying the resistance and then quantify the likely effect on field

efficacy, by providing an estimate of the resistance factor. In addition, there is a new molecular methodology that we now use routinely, that can identify a number of mutations of the target enzyme (the vitamin K epoxide reductase). We are now involved in a number of projects that are mapping the distribution of the different types of physiological resistance across the UK, and elsewhere.

I have been working on the impact and control of rodents in Pakistan, in Malaysia, in Mexico, in Chile and in the Philippines, and am currently developing links with a group in Guatemala. I am particularly interested in the non-target impact of anticoagulants on birds, and am supervising a BBSRC CASE studentship in this area. I have been the University supervisor of a number of MSc students working on mammals and birds: on the impact and eradication of alien species on Lambay Island near Dublin (3 students); on the impact and eradication of alien species on Great Salvage Island (1 student); on the habitat use and feeding ecology of native rodents in the Ifugao rice terraces in the Philippines (1 student); and on the use of social attraction techniques in an attempt to establish a Sooty Tern colony on Dennis Island in the Seychelles (4 students); plus others.

BTO 'A' ringer with training endorsement, plus endorsements to ring pulli, and use mist nets and woosh nets.

Natural England Licence Holder – Dormouse – to check nest boxes, handling and fur-clipping.

Natural England Licence Holder - Educational licence to authorise student handing of pulli Blue tit and Great tit.

Natural England Licence Holder – Bat species – to extract from mist nets, and to photograph and identify prior to release.

Associate Editor of the Journal 'Pest Management Science'

Over the past 21 years I have managed numerous Industrial R & D Contracts.

6. Current PhD Student:

Ms Laura Daniells – Research Programme entitled "Sensitivity comparison and physiological impact of 2nd generation anticoagulants against avian and rodent species"
[BBSRC CASE Studentship – Completion date December 2011]

Mr Richard Smedley – Start date: October 2011 - Research programme entitled "Bird biodiversity as an indicator of the health of the rice crop complex". Funded by a scholarship form the International Rice Research Institute.

Mr David Rymer – Start date: October 2011 - Research programme entitled "Anticoagulant resistance in the Norway rat, and its impact on field control".

7. Former PhD Students:

Dr Alex Stuart (January 2010) – Research Programme entitled "Balancing rodent pest management and rodent conservation in the Sierra Madre Biodiversity Corridor, Philippines"
[partly funded by the International Rice Research Institute, Philippines]

Dr Elaine Morgan (May 2001) - Thesis entitled "Investigation of the molecular basis of resistance in Rattus norvegicus and Mus domesticus."

Dr Chia Tio Huat (March 2000) – Thesis entitled "The susceptibility of Rattus tiomanicus, R. r. diardii and R. exulans to a number of anticoagulant rodenticides in oil palm plantations of Peninsular Malaysia."
[work based in Malaysia and funded by Zeneca]

Dr Iftikhar Hussain (May 1998) - Thesis entitled "Susceptibility to anticoagulants and the development of physiological resistance in Rattus norvegicus and Bandicota bengalensis."
[work was partly based in Pakistan and was funded by the World Bank]

8. Recent Publications and Conference Papers.

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7 U.S.C. § 136

(bb) Unreasonable adverse effects on the environment
The term “unreasonable adverse effects on the environment” means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

7 U.S.C. § 136w

(d) Scientific advisory panel
(1) In general

The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 136d(b) of this title and of the proposed and final form of regulations issued under subsection (a) of this section within the same time periods as provided for the comments of the Secretary of Agriculture under such section 136d(b) and subsection (a) of this section.